

Pharmaceuticals and Biomanufacturing

- Leveraging Traceability for Chemical Spectrophotometry through the Commercial Sector

Program: Pharmaceuticals and Biomanufacturing

Title: Leveraging Traceability for Chemical Spectrophotometry Through the Commercial Sector

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Abstract: The controlled termination of a long-standing program for the individual certification of spectrophotometric absorbance standards will capitalize on the International Organization for Standardization (ISO)/NIST description of traceability in order to stimulate a more efficient and leveraged model for supplying certified reference materials (CRMs) for absorbance.

Purpose: The Analytical Chemistry Division (ACD), recognizing that the NIST model has been successfully emulated in commercially-produced traceable CRMs, is terminating the production of individually-certified neutral-density filter Standard Reference Materials[®] (SRMs[®]) for chemical spectrophotometry. Sales of SRMs 930e, 1930, and 2930 ($0.001 < T < 0.9$, neutral-density glass filters for the visible spectrum) will cease when existing stocks are depleted. Production of SRM 2031a ($0.1 < T < 0.9$, metal-on-fused-silica neutral-density filters for the UV and visible spectral regions) will be curtailed to end sales on schedule with the glass filters.

End users are encouraged to purchase CRMs from secondary suppliers who are appropriately accredited to Guide 17025 or Guide 34 of the ISO, or who possess documentation consistent with the NIST traceability policy. Such commercial suppliers may also recertify expired NIST SRMs, although NIST ACD will continue to offer recertification for the 3500+ sets of SRM filters in the field.

Major Accomplishments: In a related move, ACD transmittance and absorbance measurements, used in solid filter recertification and future batch SRM production, will soon feature traceability through the regular transmittance scale maintained by the NIST Optical Technology Division (OTD). This will result in a single U.S. national scale for regular spectral transmittance measurements conducted in support of both physical and chemical metrology. The OTD transmittance scale is routinely compared to other national transmittance scales through measurements coordinated by the Comité Consultatif de Photométrie et Radiométrie (CCPR) of the Bureau International des Poids et Mesures (BIPM).

Impact/Future Plans: In the long term, these changes are expected to benefit affected industries (e.g. pharmaceuticals, chemical products, and health technologies) by supporting a robust and responsive system of fit-for-purpose reference materials that are manufactured by competing commercial sources. The ACD is attempting to avoid near-term anxiety in the heavily regulated pharmaceutical sector by implementing extensive educational activities during the one-to-two year period required to sell out the stocks of these filters. Such publicity includes presentations at FACSS 2004 and EAS 2004 as well as on the NIST web site and anticipated announcements in trade magazines.

References:

1. <http://ts.nist.gov/traceability/>

2. <http://www.iso.org/iso/en/ISOOnline.openerpage>
3. <http://physics.nist.gov/Divisions/Div844/facilities/specphoto/facilities.html#trans>
4. <http://www.bipm.fr/en/committees/cc/ccpr/>
5. http://www.cstl.nist.gov/nist839/839.04/2004_archive_news_items.htm#filters